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Draft Guidance on Bicalutamide

October 2024

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Active Ingredient: Bicalutamide

Dosage Form: Tablet

Route: Oral

Strength: 50 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 50 mg
   Subjects: Healthy males
   Additional comments: Female subjects should be excluded from the bioequivalence studies. Bicalutamide has a long terminal elimination half-life. Ensure adequate washout periods between treatments in the crossover studies. Applicants may also consider using a parallel study design due to bicalutamide's long half-life. For long half-life drug products, an AUC truncated to 72 hours may be used in place of AUC_{0-t} or $AUC_{0-\infty}$.

Analyte to measure: Bicalutamide, using an achiral assay

Bioequivalence based on (90% CI): Bicalutamide

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*